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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/597,005 | 08/07/2007 | Roger Graham Hall | 70360 | 4633 |

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| EXAMINER |
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JAISLE, CECILIA M

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| ART UNIT | PAPER NUMBER |
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1624

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09/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------------------|--|
| Office Action Summary | Application No. 10/597,005 | Applicant(s) ROGER GRAHAM HALL, ET AL. | |
| | Examiner Cecilia M. Jaisle | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☒ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07-06-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Lack of Unity

Applicants' election of Group IV, claims 1-16, with traverse in the May 15, 2008 Response is acknowledged. Claims 1-16 are under examination only to the extent that they are readable on Group IV, compounds of Formula (I) in which Het is 1,2,3,4-tetrazol-5-one, pesticidal compositions thereof, methods of preparation thereof and pesticidal methods therewith. Otherwise, claims 1-16 are withdrawn from examination.

Applicants traverse the Lack of Unity requirement on the basis "... that a reasonable search could go to the compounds of formula I, to the related methods of use of such compounds and to the pesticidal compositions and a process for preparation thereof." However, as pointed out in the Lack of Unity requirement of Apr. 15, 2008, a full examination of all of the claims would require a search in at least four different classes in the US classification system and the international and literature searches would be similarly extensive and burdensome. For these reasons and for all the reasons set forth in the Office Action of Apr. 15, 2008, this Lack of Unity requirement is seen to be proper and is maintained.

Rejections Under 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for control of insects, acaridae, Boophilus microplus, Nilaparvata lugens, Tetranychus urticae, Heliothis virescens, Plutella xylostella and Spodoptera littoralis, does not reasonably provide enablement to control pests, broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The term “pest” covers such a broad range of subjects that it is impossible to know what is encompassed and how to accomplish control of all species construed thereby. Pest may be considered an archaic term for pestilence, specifically, Bubonic Plague. Pest may refer to an ice hockey player specializing in aggravating opponents or the name of a British music group. Pest, referring to an organism, may construe any characteristically undesirable animal or insect, far beyond the specific organisms shown by this specification to be controlled by this method.

Applicants’ attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 66 FR 1092-1099 (2001), emphasizing that “a claimed invention must have a specific and substantial utility.” See also MPEP 2163, *et. seq.* This disclosure is not sufficient to enable the claimed methods based solely on the disclosed control of insects, acaridae, Boophilus microplus, Nilaparvata lugens, Tetranychus urticae, Heliothis virescens, Plutella xylostella and Spodoptera littoralis.

MPEP § 2164.01(a) states:

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to

Art Unit: 1624

make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue.” MPEP 2164.01(a). These factors include: (1) the claim breadth; (2) the nature of the invention; (3) the state of the prior art; (4) the level of predictability in the art; (5) the amount of direction provided by the inventor; (6) the presence of working examples; and (7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(reversing the PTO’s determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (Fed.Cir. 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement:

1. Breadth of the claims:

(a) Scope of the methods. The claims cover methods using 1,2,3,4-tetrazol-one substituted compounds of Formula (I).

(b) Scope of pests covered. The claims cover control of all subjects construed by the term “pest,” including any pestilence (e.g., Bubonic Plague), ice hockey players specializing in aggravating opponents, the British music group of that name, as well as any organism characteristically considered to be undesirable.

Considering the vast array of subjects construed by “pest, the specification fails to identify the results of treatment with the methods of this invention and how such results would be recognized.

- 2. Nature of the invention and predictability in the art:** The invention is directed toward such areas as agrochemistry and is therefore physiological in nature. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved,” and physiological activity is generally considered to be an unpredictable factor. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

In applications involving physiological activity, such as the present:

The first paragraph of 35 U.S.C. §112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

Plant Genetic Systems v. DeKalb Genetics Corp., 65 USPQ2d 1452 (CAFC 2003).

- 3. Direction and Guidance:** That provided is very limited. The dosage range information is meager at best. It is generic, the same for all pests the specification covers. No specific direction or guidance provides a regimen or dosage effective specifically for all pests construed by the claims.

- 4. State of the prior art:** Bahiense, et al., *Rev Bras Parasitol Vet.*;16 (4):243-5, reports that the fungus *Metarhizium anisopliae* controls the *Boophilus micro-plus* tick, but is silent on its ability to control other pests.

Kim, <http://www.agnet.org/library/eb/502a/>, downloaded 9/3/2008, describes control of the two-spotted spider mite *Tetranychus Urticae* by a predatory mite *Phytoseiulus Persimilis*, but is silent on its ability to control other subjects construed by “pest.”

Art Unit: 1624

Thus, ability of an agent that controls insects, acaridae, Boophilus microplus, Nilaparvata lugens, Tetranychus urticae, Heliothis virescens, Plutella xylostella and Spodoptera littoralis to control all pests construed by the claim remains open to further study and proof.

5. Working Examples: Applicants do not provide highly predictive competent evidence or recognized tests to control all pests construed by the claim.

Furthermore, Applicants have not provided competent evidence that the instantly disclosed tests are highly predictive for all pests embraced by the claim language.

6. Skill of those in the art: Bahiense and Kim call into question the efficacy of control of all pests with the claimed method. These references discussed above confirm the need for additional research.

7. Quantity of experimentation needed to make or use the invention. Based on the disclosure's content, an undue burden would be placed on one skilled in the agrochemical arts to use the invention, since the disclosure gives the skilled artisan inadequate guidance regarding pesticidal use, for reasons explained above. The state of the art, as discussed in the articles above, indicates the requirement for undue experimentation. Thus, the ability of an agent that controls insects, acaridae, Boophilus microplus, Nilaparvata lugens, Tetranychus urticae, Heliothis virescens, Plutella xylostella and Spodoptera littoralis to control all pests construed by the claim remains open to further study and proof.

Sitrick v. Dreamworks LLC, 85 USPQ2d 1826, 1830 (Fed. Cir. 2008) decided that a claim is not enabled when the claim covers multiple embodiments but the specification

Art Unit: 1624

fails to enable all embodiments. “Because the asserted claims are broad enough to cover both [embodiments], the [specification] must enable both embodiments.” Here, the claim construes many embodiments and does not enable all of them.

Automotive Tech. Int’l. v. BMW of N. America, Inc., 84 USPQ2d 1108, 1116 (Fed. Cir. 2007) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable one embodiment. “Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both [embodiments], which the specification fails to do.” Here, the claim construes many embodiments and does not enable all of them.

See MPEP 2164.01(a), discussed *supra*, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicants’ invention.

Objected Claims

Claims 1-16 are objected to as directed to both elected and non-elected subject matter. The claims should be amended to recite only elected subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**

Cecilia M. Jaisle, J.D.
9/3/2008